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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,701	07/30/2001	Terry Brady	4000-102-30CONT	8244

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SUPERVISOR PATENT PROSECUTION SERVICES
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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,701	BRADY ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-8,24-26 and 28* is/are allowed.

6)☒ Claim(s) *21-23* is/are rejected.

7)☒ Claim(s) *27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 21 and 27 are objected to because of the following informalities: On line 7 of claim 21, the phrase –at least one—should be inserted before the word "platelet" so as to recite – at least one platelet activation agonist—since claim 1, from which claim 21 depends, recites at least one platelet activation agonist. Claim 27 should be rewritten as follows so as to provide further clarification: --The method of claim 1, wherein the activity of the platelets in the physiological source is used to perform at least one selected from the group consisting of diagnosing platelet dysfunction....--. On line 3 of claim 27, the word "protectorte" should be changed to –protectorate--. Appropriate correction is required.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 21-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Spillert et al (US Patent no. 5,792,660).

Spillert et al teach of a kit comprising a first and second container. The first container contains a predetermined amount of an anticoagulant for preparing an anticoagulated blood sample. The anticoagulant can be one of sodium citrate, heparin, EDTA etc. When the anticoagulant in the first container is sodium citrate prior to receiving a blood sample, the container is devoid of any agent that would produce exogenous platelet activation/aggregation and devoid of any agent that would suppress exogenous platelet activation or aggregation. The second container in the kit contains a predetermined amount of a viscometric modulator such as collagen, platelet activating factor (PAF) etc. that serves as a platelet activation agonist. See lines 1-37 in column 7 of Spillert et al.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spillert et al in view of Ryan (cited in the last Office action). For a teaching of Spillert et al, see previous

paragraphs in this Office action. Spillert et al fail to teach that the viscometric modulator in the second container of the kit can be adenosine 5' diphosphate (ADP).

Ryan teaches of a method for determining platelet aggregation by the counting of platelets before and after exogenous platelet activation. The method comprises the first step of collecting a blood sample containing platelets in an EDTA anticoagulant, and counting the number of platelets in the blood sample to obtain an initial platelet count to serve as a baseline. This platelet count serves as a baseline since the EDTA prevents any of the platelets from becoming activated. The next step in the method is to contact the sample with an activation agonist for a period of time effective to maximally activate the activatable platelets in the sample. The activation agonist comprises calcium chloride, sodium citrate and a platelet aggregating agent. The calcium chloride and sodium citrate work together to reverse the inactivating effect that EDTA has on platelets contained in the blood sample so that the platelet aggregating agent can cause the platelets to become activated. The platelet activating agent or agonist can be collagen, adenosine diphosphate (ADP), epinephrine, ristocetin, thrombin, etc. These agonists are used in amounts capable of inducing platelet aggregation. The next step in the method is to count the number of platelets in the blood sample which has been contacted with the combination of platelet agonist materials. The platelet aggregation is then calculated from the difference in the initial platelet count from the count of platelets after contact with the agonist materials, i.e. the equation:

Platelet aggregation=(initial platelet count-platelet count after contact with agonist materials)/initial platelet count.

The platelet counts are obtained using a conventional cell counter such as a Cell Dyn 900 platelet counter based upon measuring a change in impedance.

Based upon the combination of Spillert et al and Ryan, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use ADP as the viscometric modulator in the second container of the kit taught by Spillert et al since Spillert et al teach that the viscometric modulator can be a platelet activation agonist such as collagen, and Ryan teaches that ADP is a platelet activation agonist equivalent in function to collagen.

8. Claims 1-8 and 24-28 are allowable over the prior art of record since none of the prior art of record teaches or fairly suggests a method for measuring platelet function which uses the difference between a baseline platelet count in a first sample and a count of unactivated platelets in a second sample to measure platelet function in blood from a physiological source. It is requested that Applicants add the following phrase at the end of line 7 in claim 1 in order to further define over example 1 taught by Ryan: --, wherein the first sample is essentially devoid of any agent which produces exogenous platelet activation--.

9. Applicant's arguments filed June 18, 2004 have been fully considered but they are not persuasive.

The previous objections to the disclosure and rejections of the claims under 35 USC 112, second paragraph made in the last Office action mailed on March 22, 2004 have been withdrawn in view of Applicants' amendments to the claims and specification. The previous rejection of the claims for obviousness-type double patenting over the claims in US Patent no. 6,410,337 has also been withdrawn in view of the acceptable terminal disclaimer filed on June 18, 2004. The previous rejections of the claims under 35 USC 102(b) and 35 USC 103 as being anticipated by

or obvious in view of Ryan are withdrawn in view of Applicants' persuasive argument that Ryan does not teach or fairly suggest a method for measuring platelet function which uses the difference between a baseline platelet count in a first sample and a count of unactivated platelets in a second sample to measure platelet function in blood from a physiological source. The newly presented kit claims are rejected under 35 USC 102 and 35 USC 103, as noted in paragraph nos. 4-7 above and as necessitated by amendment.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

September 7, 2004

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP [redacted] 1700